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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard J. Greff

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EXAMINER

GHALL, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

06/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/068,812

Applicant(s)

GREFF, RICHARD J.

Examiner

Isis A. Ghali

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-38 and 42, 43, 45-47 is/are pending in the application.
- 4a) Of the above claim(s) 34-38, 43 and 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-33 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No.(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No.(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 03/30/2010.

Claims 22-38, 42, 43, 45-47 are pending.

Election/Restrictions

1. This application contains claims 34-38, 43, 45-47 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 22-33 and 42 are included in the prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 22-33 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

Art Unit: 1611

had possession of the claimed invention. claim 22 as amended recites “**preformed gelatin.....** wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge **by soaking the preformed gelatin sponge in** a coating solution including the wetting agent and the **non-aqueous solvent.**”

Applicants refer to page 18, lines 5-22 for support. Recourse to the specification and page 18 in particular, applicant disclosed: “.....coating on the **preformed cross-linked gelatin foam composition**. Specifically, in this example, the wetting agents were coated onto the **cross-linked gelatin composition** in the following manner: **the wetting agent was added to a solvent**, the cross-linked gelatin composition was added to the resulting solution”. The preformed gelatin used in the present process is a “preformed gelatin composition” and not the final sponge product. Therefore, no disclosure of “wetting agent and non-aqueous solvent” or “soaking preformed gelatin sponge” as instantly claimed.

If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 22-25, 27-30, 32, 33, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Pawelchak et al. (US 4,292,972, IDS filed 03/06/2003).

Current claim 22 is directed to a composition comprising: a cross-linked gelatin sponge and a wetting agent that is soluble in a non-aqueous solvent wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent.

Pawelchak disclosed sponge product comprising hemostatic bioabsorbable cross-linked gelatin foam (abstract; col.3, lines 18-22, 30-33, 44-46; the claims). The product comprises from about 10% surface tension modifier including polyoxyethylene derivatives of sorbitan fatty acid esters, such as Tween 60 (col.4, lines 47-56). The surface active agents disclosed by the reference are identical to those instantly claimed as wetting agents, and inherently are soluble in non-aqueous solvents. Pawelchak further disclosed up to 30% glycerin (col.5, lines 35-40; examples 6 and 18), which also reads on wetting agent and inherently are soluble in non-aqueous solvents. The reference disclosed method of making the foam by forming dispersion containing aerated foamed gelatin, which reads on preformed gelatin, and adding the surfactant and/or glycerin to the dispersion, followed by drying of the dispersion and forming a sponge product (col.4, lines 40-47, 60-68; col.5, lines 1-2). Adding the surfactant and/or glycerin to the dispersion containing foamed aerated gelatin meet the limitation of

coating the gelatin with the wetting agent as instantly claimed by claim 22 because applicants coated the gelatin foam by soaking the foam in dispersion containing the wetting agent. The product is sterilized and packaged (col.5, lines 3-8). Although reduction of the hydration time is directed to the intended use of the product, however, the product disclosed by the reference that comprises cross-linked gelatin and the same wetting agent inherently decreases the hydration time of the cross-linked gelatin that claimed in claim 22. The foamed sponge further comprises antimicrobial agent and hemostatic agent such as thrombin (col.5, lines 29-35). The solubility and absorbability of the foam product can be reduced by reducing cross-linking (col.3, lines 36-39).

Response to Arguments

6. Applicant's arguments filed 03/30/2010 have been fully considered but they are not persuasive.

Applicant argues that Pawelchak does not disclose a preformed gelatin sponge soaked in a coating solution including the wetting agent and a non-aqueous solvent. Pawelchak discloses that the wetting agent is added to the disclosed aqueous colloidal dispersion prior to freezing and drying. Furthermore, Applicant argues that the freezing and drying steps of Pawelchak are necessary to form the foam sponge, and thus the wetting agent is not coated (as a coating solution including the wetting agent and a non-aqueous solvent) on at least a substantial portion of the surface of a preformed gelatin sponge, as in the pending claim.

In response to this argument, it is argued that it is argued that the reference clearly discloses method of making the foam by forming dispersion containing **aerated foamed gelatin**, which reads on preformed, and adding the surfactant and glycerin to the dispersion read on non-aqueous solvent and wetting agent added to the gelatin composition, followed by drying of the dispersion and forming a sponge product (col.4, lines 40-47, 60-68; col.5, lines 1-2). Adding the surfactant and/or glycerin to the dispersion containing foamed aerated gelatin meet the limitation of coating the gelatin with the wetting agent by soaking as instantly claimed by claim 22 because applicants coated the gelatin foam by soaking the foam in the wetting agent. In any event, the present claims are directed to composition and all the elements of the composition are taught by the prior art. The limitation of "coating the gelatin sponge by soaking in" is directed to method of making the composition that does not impart patentability to composition claims. The present claims recite evaporating the solvent and this means the final product does not include the solvent. The present product is gelatin sponge and wetting agent substantially coated on the sponge as taught by the reference. The present claims are considered by "product by process claim", and product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re*

Art Unit: 1611

Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), wherein the product-by-process claim was rejected because the end product, in both the prior art and the claimed product were the same. The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Gamero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Since the claimed product appears to be substantially identical to that of the prior art, the burden is shifted to applicant to show an unobvious difference between the claimed product and the prior art product and to come forward with evidence establishing an unobvious difference. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974); *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983); *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). It has been held that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459

Art Unit: 1611

F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The reference process provided gelatin sponge coated with wetting agent as instantly claimed.

The present claims' language does not exclude the step of freeze drying taught by the reference. The present specification disclosed drying, and the present claims does not exclude freeze drying. The examiner does not understand the argument that "the freezing and drying steps of Pawelchak are necessary to form the foam sponge, and thus the wetting agent is not coated (as a coating solution including the wetting agent and a non-aqueous solvent) on at least a substantial portion of the surface of a preformed gelatin sponge".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak et al. in view of JP 02-182259 ('259).

The teachings of Pawelchak are discussed above.

Although Pawelchak teaches anionic surfactants, however, does not explicitly teach alkyl (C_6 - C_{20}) sulfate salts, aryl (C_6 - C_{10}) sulfate salts, and alkaryl (C_7 C_{24}) sulfate salts as claimed by claim 26.

JP '259 teaches composition comprising cross linked gelatin impregnated with surfactant (abstract). The surfactants include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph).

Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to provide hemostatic composition comprising cross linked gelatin sponge and anionic surfactant (wetting agent) as taught by Pawelchak, and replace the anionic surfactant with sodium lauric sulfuric acid taught by JP '259. One

would have been motivated to do so because JP '259 teaches the equivalency between sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester as anionic surfactant added to the hemostatic gelatin sponge product. One would reasonably expected formulating hemostatic composition comprising cross linked gelatin foam and sodium lauric sulfuric acid that has hemostatic effect.

Response to Arguments

11. Applicant's arguments filed 03/30/2010 have been fully considered but they are not persuasive. Applicant argues that Yasushi does not remedy the shortcomings of Pawelchak with respect to claim 22.

In response to this argument, it is argued that Yaushi is relied upon for the solely teaching of specific wetting agents as claimed by claim 26.

12. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak in view of EP 5568 334 ('334).

The teachings of Pawelchak are discussed above.

Although Pawelchak teaches hemostatic agents incorporated into the gelatin foam product, however the reference does not specifically teach growth factor as claimed by claim 31.

EP '334 teaches sponge comprising cross linked gelatin and active agent, preferably growth factors which enhances wound healing and nerve regeneration (abstract; col.5, lines 22-30).

Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to provide hemostatic product comprising cross linked gelatin sponge, anionic surfactant and hemostatic agents as taught by Pawelchak, and add the growth factor taught EP '334 to the sponge. One would have been motivated to do so because EP '334 teaches that growth factors are preferred active ingredient to be added to hemostatic wound treating composition comprising gelatin because growth factors enhance wound healing and nerve regeneration. One would reasonably expected formulating composition comprising cross linked gelatin foam, anionic surfactant and growth factors wherein the composition successfully and effectively enhances wound healing and nerve regeneration.

Response to Arguments

13. Applicant's arguments filed 03/30/2010 have been fully considered but they are not persuasive. Applicant argues that Song does not remedy the shortcomings of Pawelchak with respect to claim 22.

In response to this argument, it is argued that Song is relied upon for the solely teaching of inclusion of growth factor in wound dressing as claimed by claim 31.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1611

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1611

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611